UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/451,566	11/30/99	ITO	07898-051001

020985
FISH & RICHARDSON, PC
4350 LA JOLLA VILLAGE DRIVE
SUITE 500
SAN DIEGO CA 92122

HM12/0525

EXAMINER
FURMAN, B

ART UNIT	PAPER NUMBER
1655	21

DATE MAILED: 05/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/451,666	Applicant(s) ITO ET AL.	
	Examiner BJ Forman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-12 and 21-23* is/are pending in the application.

4a) Of the above claim(s) *9-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-8 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☒ Interview Summary (PTO-413) Paper No(s). *21* .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 10 May 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/451,666 is acceptable and a CPA has been established. An action on the CPA follows.

2. This action is in response to papers filed 10 May 2001 in Paper No. 19 in which originally elected claims 1-3 and non-elected claims 16-20 were canceled, originally non-elected claims 4-8 were amended and new claims 21-13 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 11 dated 7 July 2000 are withdrawn in view of the amendments.

New grounds for rejection are discussed.

Currently claims 4-8 and 21-23 are under prosecution and claims 9-12 are withdrawn from prosecution.

Claim Objections

3. Claim 7 is objected to because of the following informalities: the comma is missing in line 3 following lysine. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4-8 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 4, 6-8, 21 and 23 are indefinite in Claim 4 for the recitation "spotting mixtures of respective probes and the binding agent on the plate" because "respective" is a relational term, but it is unclear what relationship is being defined. The recitation is also indefinite because it is unclear whether the method comprises one step of spotting. The recitation is further indefinite because it is unclear whether "spotting" describes the resulting appearance or a method step of spotting. It is suggested that Claim 4 be amended to clarify e.g. "binding mixtures of probes and binding agent onto the plate at locally spotted positions" (specification, page 4, lines 1-16).

b. Claims 4-23 are indefinite in Claims 5 and 22 for the recitations "spotting a binding agent" and "spotting the probes" because it is unclear whether "spotting" describes the resulting appearance or a method step of spotting. It is suggested that Claims 5 and 22 be amended to clarify e.g. replace "spotting" with "binding".

c. Claims 4-23 are indefinite in Claims 5 and 22 because it is unclear whether the method comprises one step of spotting or two. It is suggested that Claim 5 and 22 be amended to clarify e.g. in line 5 after "spotting the probes" insert "onto the binding agent spotted".

d. Claims 5, 6-7, 21 and 23 are indefinite in Claim 5 for the recitation "where the binding agent is spotted with a spotting pin" because it is unclear whether the binding agent or probe is "spotted with a spotting pin". It is suggested that the claim be amended to clarify e.g. before "with a spotting pin" insert "wherein the probes are spotted"

e. Claims 22, 6-7 and 23 are indefinite in Claim 22 for the recitation "probes are to be spotted with a tube" because it is unclear whether the "probes" are "spotted with a tube". It is suggested that Claim 22 be amended to clarify e.g. before "with a tube" insert "wherein the binding agent is spotted".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 4-8 and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Beattie U.S. Patent No. 5,843,767, issued 1 December 1998).

Regarding Claim 4, Beattie et al. disclose a method for producing a biochip, the method comprising: spotting mixtures of probes and the binding agent on the plate (Column 6, lines 21-26).

Regarding Claim 5, Beattie et al. disclose a method for producing a biochip by spotting probes on a plate the method comprising: spotting a binding agent for binding the probes to the plate at positions where the probes are to be; and spotting the probes on the plate at positions where the binding agent is spotted with a spotting pin (Column 13 line 51-Column 14, line 11).

Regarding Claim 6, Beattie et al. disclose the methods of Claims 4 and 5 wherein the plate is glass (Column 13, lines 55-64).

Regarding Claim 7, Beattie et al. disclose the methods of Claims 4 and 5 wherein the binding agent is silylation-coating (Column 13, lines 55-64).

Regarding Claim 8, Beattie et al. disclose the methods of Claim 4 wherein the mixtures are spotted using a spotting pin i.e. rod (Column 14, lines 16-28).

Regarding Claim 23, Beattie et al. disclose the methods of Claim 5 and 8 wherein the plate is substantially planar i.e. glass slide (Column 13, lines 55-64).

8. Claims 4-6, 8 and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mirzabekov et al. (U.S. Patent No. 6,143,499, filed 19 June 1998).

Regarding Claim 4, Mirzabekov et al. disclose a method for producing a biochip, the method comprising: spotting mixtures of probes and the binding agent (i.e. gel) on the plate (Column 4, lines 50-61) wherein the binding agent is a spot on the plate and therefore the binding agent is spotted on the plate.

Regarding Claim 5, Mirzabekov et al. disclose a method for producing a biochip by spotting probes on a plate the method comprising: spotting a binding agent (i.e. gel) for binding the probes to the plate at positions where the probes are to be spotted wherein the binding agent is a spot on the plate and therefore the binding agent is spotted on the plate (Column 11, lines 40-67); and spotting the probes on the plate at positions where the binding agent is spotted with a spotting pin (Column 9, lines 45-62).

Regarding Claim 6, Mirzabekov et al. disclose the method wherein the plate is glass (Column 11, lines 40-45).

Regarding Claim 8, Mirzabekov et al. disclose the method wherein the mixtures are spotted using a spotting pin i.e. rod (Column 9, lines 45-50 and Fig. 9).

Regarding Claim 23, Mirzabekov et al. disclose the methods of Claim 5 and 8 wherein the plate is substantially planar i.e. glass slide (Column 11, lines 40-45).

9. Claims 4-8 and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bradley et al. (WO 99/57323, published 11 November 1999).

Regarding Claim 4, Bradley et al. disclose a method for producing a biochip, the method comprising: spotting mixtures of probes and the binding agent (i.e. silane-modification) on the plate (page 13, lines 3-20 and page 15, lines 24-33).

Regarding Claim 5, Bradley et al. disclose a method for producing a biochip, the method comprising: spotting mixtures of probes and the binding agent (i.e. silane-modification) on the plate (page 13, lines 3-20 and page 15, lines 24-33). The claim is drawn to a method for producing a biochip comprising spotting a binding agent and spotting probes. However, it is unclear whether the method comprises two separate steps of spotting or one. Therefore, for purposes of examination, the claim, given the broadest reasonable interpretation to be encompassed by the teaching of Bradley et al. who disclose the method comprising a single step of spotting.

Regarding Claim 6, Bradley et al. disclose the method of Claim 4 wherein the plate is glass (page 14, lines 10-17).

Regarding Claim 7, Bradley et al. disclose the method of Claim 4 wherein the binding agent is silylation-coating (page 13, lines 3-20).

Regarding Claim 8, Bradley et al. disclose the method of Claim 4 wherein the mixtures are spotted using a spotting pin (page 15, lines 24-33).

Regarding Claim 23, Bradley et al. disclose the method of Claim 8 wherein the plate is substantially planar i.e. glass slide (page 14, lines 10-17).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843,767, issued 1 December 1998) in view of Shalon et al. (U.S. Patent No. 6,110426, filed 30 December 1997).

Regarding Claim 21, Beattie et al. teach the methods for producing a biochip by spotting probes on a plate the method comprising: spotting a binding agent for binding the probes to the plate at positions where the probes are to be; and spotting the probes on the plate at positions where the binding agent is spotted with a spotting pin i.e. needle (Column 13 line 51-Column 14, line 11) but they do not teach the spotting pin comprises at least one recessed tip. Shalon et al. teach a similar method for producing a biochip comprising spotting probes on a plate at positions where the binding agent is located (Column 7, lines 36-46) wherein the spotting pin comprises at least one recessed tip (Column 7, lines 3-17). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the needle pin of Beattie et al. with the spotting pin having a recessed tip to thereby both fill and dispense from the pin using simple capillary action (Column 7, line 55-Column 8, line 9) for the expected benefit efficiency and economy of reagents i.e. depositing pl to nl volumes of probe in a repeatable fashion as taught by Shalon et al. (Column 9, lines 1-3).

12. Claims 22-23 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (U.S. Patent No. 5,843,767, issued 1 December 1998) in view of Gordon et al. (U.S. Patent No. 5,601,980, issued 11 February 1007).

Regarding Claim 22, Beattie et al. teach a method for producing a biochip by spotting probes on a plate the method comprising: spotting a binding agent for binding the probes to the plate at positions where the probes are to be; and spotting the probes on the plate at positions where the binding agent is spotted with a spotting pin (Column 13 line 51-Column

14, line 11) but they do not teach spotting with a tube. Gordon et al. teach the similar method for producing a biochip comprising spotting with a tube i.e. a micropipette comprising a tube (Column 4, lines 12-23). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the tube spotting apparatus of Gordon et al. to the spotting technique of Beattie et al. for the expected benefit of accurately spotting miniscule volumes and for the additional benefit of cost effective production of biochips as taught by Gordon et al. (Column 3, lines 52-57).

Regarding Claim 23, Beattie et al. teach their method wherein the plate is substantially planar i.e. glass slide (Column 13, lines 55-64).

Regarding Claim 6, Beattie et al. teach their method wherein the plate is glass (Column 13, lines 55-64).

Regarding Claim 7, Beattie et al. teach their method wherein the binding agent is silylation-coating (Column 13, lines 55-64)

13. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mirzabekov et al. (U.S. Patent No. 6,143,499, filed 19 June 1998) in view of Shalon et al. (U.S. Patent No. 6,110426, filed 30 December 1997).

Regarding Claim 21, Mirzabekov et al. teach a method for producing a biochip by spotting probes on a plate the method comprising: spotting a binding agent (i.e. gel) for binding the probes to the plate at positions where the probes are to be spotted wherein the binding agent is a spot on the plate and therefore the binding agent is spotted on the plate (Column 11, lines 40-67); and spotting the probes on the plate at positions where the binding agent is spotted with a spotting pin (Column 9, lines 45-62) but they do not teach the spotting pin comprises at least one recessed tip. Shalon et al. teach a similar method for producing a biochip comprising spotting probes on a plate at positions where the binding agent is located

(Column 7, lines 36-46) wherein the spotting pin comprises at least one recessed tip (Column 7, lines 3-17). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the needle pin of Mirzabekov et al. with the spotting pin having a recessed tip to thereby both fill and dispense from the pin using simple capillary action (Column 7, line 55-Column 8, line 9) for the expected benefit efficiency and economy of reagents i.e. depositing pl to nl volumes of probe in a repeatable fashion as taught by Shalon et al. (Column 9, lines 1-3)

14. Claims 22-23 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirzabekov et al. (U.S. Patent No. 6,143,499, filed 19 June 1998) in view of Gordon et al. (U.S. Patent No. 5,601,980, issued 11 February 1007).

Regarding Claim 22, Mirzabekov et al. teach a method for producing a biochip by spotting probes on a plate the method comprising: spotting a binding agent (i.e. gel) for binding the probes to the plate at positions where the probes are to be spotted wherein the binding agent is a spot on the plate and therefore the binding agent is spotted on the plate (Column 11, lines 40-67); and spotting the probes on the plate at positions where the binding agent is spotted with a spotting pin (Column 9, lines 45-62) but they do not teach spotting with a tube. Gordon et al. teach the similar method for producing a biochip comprising spotting with a tube i.e. a micropipette comprising a tube (Column 4, lines 12-23). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the tube spotting apparatus of Gordon et al. to the spotting technique of Mirabekov et al. for the expected benefit of accurately spotting miniscule volumes and for the additional benefit of cost effective production of biochips as taught by Gordon et al. (Column 3, lines 52-57).

Regarding Claim 23, Mirzabekov et al. teach their method wherein the plate is substantially planar i.e. glass slide (Column 11, lines 40-45).

Regarding Claim 6, Mirzabekov et al. teach their method wherein the plate is glass (Column 11, lines 40-45).

15. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mirzabekov et al. (U.S. Patent No. 6,143,499, filed 19 June 1998) in view of Gordon et al. (U.S. Patent No. 5,601,980, issued 11 February 1007) as applied to Claims 22-23 and 6 above and further in view of Beattie U.S. Patent No. 5,843,767, issued 1 December 1998).

Regarding Claim 7, Mirzabekov et al. disclose a method for producing a biochip by spotting probes on a plate the method comprising: spotting a binding agent (i.e. gel) for binding the probes to the plate at positions where the probes are to be spotted wherein the binding agent is a spot on the plate and therefore the binding agent is spotted on the plate (Column 11, lines 40-67); and spotting the probes on the plate at positions where the binding agent is spotted with a spotting pin (Column 9, lines 45-62) but they do not teach the binding agent is spotted with a tube and selected from the group consisting of poly-l-lysine, carbodiimide and silylation-coating. Beattie et al. teach the similar method wherein the binding agent is silylation-coating (Column 13, lines 55-64). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify binding agent of Mirzabekov et al. with the silylation coating of Beattie et al. for the expected benefit of covalently binding the probe to the plate as taught by Beattie et al. (Column 4, lines 40-52). Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the spotting technique of Mirzabekov et al. using routine experimentation apply the binding agent locally using a tube for the expected benefit of optimizing gel application to thereby maximize experimental results.

16. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradley et al. (WO 99/57323, published 11 November 1999) in view of Shalon et al. (U.S. Patent No. 6,110426, filed 30 December 1997).

Regarding Claim 21, Bradley et al. teach method for producing a biochip, the method comprising: spotting mixtures of probes and the binding agent (i.e. silane-modification) on the plate (page 13, lines 3-20 and page 15, lines 24-33) but they do not teach the spotting pin comprises at least one recessed tip. Shalon et al. teach a similar method for producing a biochip comprising spotting probes on a plate at positions where the binding agent is located (Column 7, lines 36-46) wherein the spotting pin comprises at least one recessed tip (Column 7, lines 3-17). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the pin of Bradley et al. with the spotting pin having a recessed tip to thereby both fill and dispense from the pin using simple capillary action (Column 7, line 55-Column 8, line 9) for the expected benefit efficiency and economy of reagents i.e. depositing pl to nl volumes of probe in a repeatable fashion as taught by Shalon et al. (Column 9, lines 1-3).

17. Claims 22-23 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradley et al. (WO 99/57323, published 11 November 1999) in view of Gordon et al. (U.S. Patent No. 5,601,980, issued 11 February 1007).

Regarding Claim 22, Bradley et al. teach method for producing a biochip, the method comprising: spotting mixtures of probes and the binding agent (i.e. silane-modification) on the plate (page 13, lines 3-20 and page 15, lines 24-33) but they do not teach spotting with a tube. Gordon et al. teach the similar method for producing a biochip comprising spotting with a tube i.e. a micropipette comprising a tube (Column 4, lines 12-23). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the tube

spotting apparatus of Gordon et al. to the spotting technique of Bradley et al. for the expected benefit of accurately spotting miniscule volumes and for the additional benefit of cost effective production of biochips as taught by Gordon et al. (Column 3, lines 52-57).

Regarding Claim 23, Bradley et al. teach their method wherein the plate is substantially planar i.e. glass slide (page 14, lines 10-17).

Regarding Claim 6, Bradley et al. teach their method wherein the plate is glass (page 14, lines 10-17).

Regarding Claim 7, Bradley et al. teach their method wherein the binding agent is silylation-coating (page 13, lines 3-20).

Prior Art

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Caren et al. (U.S. Patent No. 6,221,653, filed 27 April 1999) disclose a method for producing a biochip comprising: spotting probes and binding agents on a plate (Column 8, lines 8-22).

Brennan (U.S. Patent No. 6,210,894, filed 18 May 2001) disclose a method for producing a biochip comprising: spotting probes and binding agents on a plate (Examples 1 and 3).

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
May 24, 2001

CARLA J. MYERS
PRIMARY EXAMINER